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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,191	12/19/2000	Liang-Chang Dong	ARC 2556N1	7458

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/740,191	Applicant(s) DONG ET AL.	
	Examiner Humera N Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 06/11/02.

Claims 12-24 are pending. Claims 12-24 remain rejected.

Claim 1 has been cancelled.

The previous Amendment filed 01/22/02 was not entered because it appeared that the Amendment was not related to or pertinent to this case.

Note: The applicant's instant claims under examination are pending claims 12-24.

In view of the cancellation of claim 1, the Double Patenting rejection of claim 1 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14, 17-18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckenhoff *et al.* (US Pat. No. 4, 663,148) (collectively, "Eckenhoff").

Eckenhoff disclose a dispenser for delivering a beneficial agent to an environment of use (see claim 1). The dispenser comprises (a) a container comprising a gelatin cap and body [read capsule]; (b) a composition comprising a beneficial drug and a temperature-sensitive means for forming a dispensable composition in a biological environment selected from the group consisting of a butter, wax, stearate, hydrogenated oil, partially hydrogenated oil, glyceride, glycol, ester and polyether [read liquid drug layer comprising a drug and a member selected from the group consisting of a mono- and di- glyceride]; (c) means in the container for occupying an increasing volume in the compartment [read expandable layer which expands upon contact with fluid]; (d) a wall surrounding the container comprising at least in part a semi-permeable composition; (e) at least one passageway in the dispenser.

Eckenhoff disclose the ingredients that make up the semi-permeable wall (see reference column 8, line 62 through col. 10, line 14). Eckenhoff disclose the ingredients that make up the swellable, expandable inner member, including polymeric materials and osmagents (see col. 10, line 15 through col. 11, line 34). The ingredients that make up the temperature-sensitive means, which include surfavtants and mono- and di-glycerides are also disclosed (col.11, line 35 through col. 12, line 45). These disclosures meet the limitations of applicants' claims 12, 14, 17, 18, 20 and 23.

Claims 12-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong *et al.* (US Pat. No. 5, 324,280) (collectively, "Wong").

Wong disclose an osmotic system for delivering a beneficial formulation to an environment of use. In claim 1, Wong disclose an osmotic system comprising:

(a) a capsule

(b) a dosage amount of a beneficial agent liquid formulation

(c) an osmagent composition

(d) a semi-permeable composition

(e) at least one orifice that communicates with the exterior and the lumen.

Wong disclose the ingredients that make up the beneficial agent liquid formulation (col. 10, line 60 through col. 12, line 47 – active agents); (col. 12, line 48 through col. 13, line 22 – mono- and di- glycerides and surfactants). This disclosure meets the limitations of applicants' claims 12, 14, 16-18, 20, 22 and 23. In examples 1, 6-8 and 7, a wall-forming semi-permeable composition comprising cellulose acetate and polyethylene glycol is disclosed. This disclosure meets the limitations of applicants' claims 15 and 21. The ingredients that make up the hydro-activated layer, including osmopolymers amd osmagents are disclosed (col. 8, line 48 through col. 10, line 2). In example 10, Eckenhoff disclose an osmotic composition comprising polyvinylpyrrolidone and hydroxypropylmethylcellulose. This meets the applicants' limitations of claims 13 and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 14, 17, 18, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff *et al.*

Eckenhoff teach a dispenser for delivering a beneficial agent to an environment of use (see claim 1). The dispenser comprises (a) a container comprising a gelatin cap and body; (b) a composition comprising a beneficial drug and a temperature-sensitive means; (c) means in the container for occupying an increasing volume in the compartment; (d) a wall surrounding the container comprising at least in part a semi-permeable composition; (e) at least one passageway in the dispenser. The ingredients that make up the temperature-sensitive means include surfactants and mono- and di-

glycerides. Therefore, it would have been obvious for one of ordinary skill in the pharmaceutical art at the time the invention was made to formulate a dispenser containing a beneficial drug composition to be dispersed into the environment. The expected result would be a thermo-responsive, hydrophobic composition comprising insoluble to soluble drugs and in which thermo-responsive composition in response to the temperature of the biological environment changes its form and becomes fluid, semi-solid or the like for enhanced delivery from the dispenser.

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong *et al.* as discussed above.

Wong teach an osmotic system for delivering a beneficial formulation to an environment of use. The osmotic system comprises: (a) a capsule; (b) a dosage amount of a beneficial agent liquid formulation; (c) an osmagent composition; (d) a semi-permeable composition; (e) at least one orifice that communicates with the exterior and the lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate an osmotic system for delivering at a controlled rate, a beneficial formulation to a fluid environment of use based on the teachings of Wong. The expected result would be an osmotic system manufactured in the form of an osmotic device for delivering in vivo a beneficial liquid drug formulation, such as a lipophilic drug formulation that is difficult to deliver (col. 2, lines 15-21).

Wong while teaching an osmotic system comprising a beneficial formulation, do not explicitly teach the temperature at which the semi-permeable composition softens. It is the position of the examiner that the semi-permeable composition of Wong softens at the same or a similar temperature as the applicant's membrane since the ingredients contained in the prior art are the same, therefore they could also allow for similar properties.

Response to Arguments

Applicant's arguments filed 06/11/02 have been fully considered but they are not persuasive. The applicant argued, "Eckenhoff et al. and Wong et al. fail to expressly or inherently teach a dosage form comprising a self-emulsifying drug formulation."

This argument is not found to be persuasive and the examiner points out that the prior art discloses a formulation comprising mono- and di- glycerides. The properties of oils are to form an emulsion upon coming in contact with water or an aqueous phase. The applicant has not shown that the prior art compositions do not form an emulsion by not coming in contact with water or an aqueous phase.

The applicant argued, "Neither of the references cited in the Office Action provides evidence to sufficient to properly establish the *prima facie* obviousness and that neither Eckenoff nor Wong teach or suggest a dosage form including a self-emulsifying drug formulation."

These arguments are not found to be persuasive since the prior art teach or suggest a dosage formulation similar to that as instantly claimed. The instant invention is drawn to a sustained-release liquid formulation dosage form comprising: a capsule comprising an expandable layer, which expands upon contact with fluid; and a self-emulsifying drug formulation. The prior art teaches a dispenser for delivering a beneficial ingredient, comprising a telescopic capsule, wherein the dispenser contains an expandable member. The dispenser is self-contained, self-starting and self-powered in fluid environments. Furthermore, the prior art teaches such a formulation comprising insoluble to soluble drugs, and the teaching of mono- and di- glycerides. Glycerides are oils, which upon contact with water form an emulsion. The applicant has not shown that the prior art does not form an emulsion. The teaching of mono- and di- glycerides meets the applicant's limitations of a self-emulsifying drug formulation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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